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10/080,772

02/22/2002

Janet K. Yamamoto

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PARKIN, JEFFREY S

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No.: 10/080,772
Applicants: Yamamoto, J. K., et al.

Docket No.: UF-267XC1
Filing Date: 02/22/2002

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 27 May, 2008. Claims 1-14 and 47-50 are pending in the instant application.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 and 47-50 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. As previously set forth, the claims are directed toward a method for inducing an immune response to feline immunodeficiency virus (FIV) in a human or non-feline that is susceptible to infection by FIV, through the administration of an FIV immunogen. The reference to an "immune response" is vague and indefinite. First, the nature of the immune response (i.e., protective, therapeutic,

humoral, cell-mediated, complement, etc.) desired is not readily manifest. Second, FIV is a lentivirus that is specific for felines. The virus does not establish productive viral infections in non-feline hosts, including humans (Poeschla and Looney, 1998; Butera *et al.*, 2000). Thus, it is not readily manifest what purpose the immune response serves. Finally, the claims are also incomplete for omitting essential steps, such omission amounting to a gap between the steps. See M.P.E.P. § 2172.01. The claims fail to recite any positive methods steps following the administration step that result in the confirmation of the desired immune response. For instance, if the claims were directed toward a method of inducing cross-neutralizing antibodies between FIV and HIV-1, the methods would generally comprising an administration step and minimally, a detection step to identify if said antibodies were present in the host. Appropriate correction and clarification are required.

Applicants traverse and submit the claims are clear and unambiguous. It was argued that the term "immune response" could encompass any type of immune response. It was also argued that sufficient method steps were provided. These arguments are not deemed to be persuasive for the reasons immediately set forth *supra*.

35 U.S.C. § 101

The following is a quotation of 35 U.S.C. § 101 which reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of

matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 1-14 and 47-50 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by a specific, substantial, and/or credible utility, or a well-established utility. As previously set forth, the claims are drawn toward a method for inducing an immune response to feline immunodeficiency virus (FIV) in a human or a non-feline that is susceptible to infection by FIV, through the administration of an FIV immunogen. FIV is a lentivirus that is specific for felines. The virus does not establish productive viral infections in non-feline hosts, including humans (Poeschla and Looney, 1998; Butera et al., 2000). Butera and colleagues (2000) examined a cohort of veterinarians for exposure to both FIV and FeLV and concluded that "The absence of identifiable feline retroviral zoonosis among this highly exposed cohort strongly supports the view that these feline viruses pose little threat to individual humans or to public health" (see left column, p. 1478). Poeschla and Looney (1998) reviewed the prior art and noted that "Neither human seroconversion nor any other detectable evidence of human infection or disease occurs, despite frequent exposure of humans to FIV by biting, the principal route of natural feline transmission" (see bridging paragraph, p. 6858). The term "infection" references the characteristic of a disease-causing agent that is capable of entering, multiplying, surviving, and causing disease in the host.¹ The purpose of inducing an immune response appears to be

¹ Stedman's Online Medical Dictionary, 2008, Lippincott Williams & Wilkins; Merriam-Webster Online Dictionary, 2005, Merriam-Webster, Incorporated.

for the purpose of preventing and/or treating infection (see specification, p. 10). No other uses are disclosed in the specification. However, since FIV does not establish a productive infection in non-feline hosts and said hosts are clearly not susceptible to infection by FIV, it is not readily manifest what purpose the induction of an immune response in this setting serves. Accordingly, the claimed invention lacks both a specific and substantial utility.

Applicants contend that FIV is capable of infecting humans, as well as, macaques. First, concerning the two examples set forth in the specification, neither one demonstrates that FIV is capable of productively infecting humans. In fact, it appears that the infective process, was in fact aborted. This may be due to the inability of human cells to support FIV replication, infection with an effete strain of FIV, or a strong and robust immune response. The disclosure does not address these possibilities. Thus, it is not readily manifest how administering FIV to a non-human or human host that does not support FIV replication will prove useful.

Claims 1-14 and 47-50 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1-14 and 47-50 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As discussed *supra*, the claims are drawn toward a method for inducing an immune response to feline immunodeficiency virus (FIV) in a human or non-feline that is susceptible to infection by FIV, through the administration of an FIV immunogen. The purpose of inducing an immune response appears to be for the purpose of preventing and/or treating infection (see specification, p. 10). No other uses are disclosed in the specification.

The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of

the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

1) The disclosure fails to provide sufficient guidance demonstrating that humans, and other non-felines, are productively infected by FIV. The term "infection" references the characteristic of a disease-causing agent that is capable of entering, multiplying, surviving, and causing disease in the host.² FIV is a lentivirus that is specific for felines. The virus does not establish productive viral infections in non-feline hosts, including humans (Poeschla and Looney, 1998; Butera et al., 2000). Butera and colleagues (2000) examined a cohort of veterinarians for exposure to both FIV and FeLV and concluded that "The absence of identifiable feline retroviral zoonosis among this highly exposed cohort strongly supports the view that these feline viruses pose little threat to individual humans or to public health" (see left column, p. 1478). Poeschla and Looney (1998) reviewed the prior art and noted that "Neither human seroconversion nor any other detectable evidence of human infection or disease occurs, despite frequent exposure of humans to FIV by biting, the principal route of natural feline transmission" (see bridging paragraph, p. 6858). Thus, the induction of an immune response for therapeutic or prophylactic purposes seems unlikely.

2) The disclosure fails to provide sufficient guidance or direction pertaining to the nature of the desired immune response. As note *supra* in item (1), FIV does not establish a

² Stedman's Online Medical Dictionary, 2008, Lippincott Williams & Wilkins; Merriam-Webster Online Dictionary, 2005, Merriam-Webster, Incorporated.

productive infection in human or non-feline hosts. Thus, it is not readily manifest what type of immune response the induction of an FIV immunogen will produce (i.e., humoral, cell-mediated, neutralizing antibody, cytotoxic T-lymphocyte (CTLJ), complement, etc.).

3) The disclosure fails to provide any working embodiments. It was reported in the disclosure that two human subjects generated antibodies specific for FIV suggesting previous exposure to FIV. However, the specification clearly states that "Both of the human subjects infected with FIV identified thus far are currently clinically and immunologically asymptomatic" (see specification, p. 8). Thus, the data provided in the specification clearly demonstrates that FIV does not establish a productive infection in human hosts. This may be due, inter alia, to the inability of human cells to support FIV replication, the absence of suitable receptors and coreceptors on the cell surface of human cells, or the generation of a robust immune response that clears the virus before it can establish a productive infection. In any event, the disclosure fails to provide any working embodiments wherein an FIV immunogen was administered to induce a protective or therapeutic immune response against FIV.

4) The prior art demonstrates that FIV does not productively infect humans or non-felines (see item (1) *supra*). Thus, it is not readily manifest what type of immune response should be generated by the claimed invention.

Accordingly, when all the aforementioned items are considered *in toto*, it would clearly require undue experimentation to practice the claimed invention.

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Applicants again contend that FIV is capable of infecting humans, as well as, macaques. First, concerning the two examples set forth in the specification, neither one demonstrates that FIV is capable of productively infecting humans. In fact, it appears that the infective process, was in fact aborted. This may be due to the inability of human cells to support FIV replication, infection with an effete strain of FIV, or a strong and robust immune response. The disclosure does not address these possibilities. Thus, it is not readily manifest how administering FIV to a non-human or human host that does not support FIV replication will prove useful.

Action Is Final, Necessitated by Amendment

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

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Respectfully,

/Jeffrey S. Parkin, Ph.D./
Primary Examiner, Art Unit 1648

15 September, 2008